

REMARKS

The Applicants appreciate the Examiner's thorough examination of the subject application. Applicants request reconsideration of the subject application based on the following remarks.

Claims 1 thru 11 are currently pending in the application. Claims 1, 2, 3, 5, 6, 8, 9, 10 and 11 have been amended. Claims 4na 7 have been canceled

Support for the amendments to the claims can be found throughout the application as filed. No new matter has been added by the amendments to the specification or the claims.

Claims 1-11 were rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner maintains that, in claims 1-11, the term "soluble film" is vague since it is not stated in the claims if the film is water soluble, alcohol soluble, alkaline soluble or soluble in some other type of liquid or substance, which renders all the claims indefinite.

Claims 1-11 have all been amended to recite "water" soluble film. As noted throughout the application, the film preparations of the present invention are rapidly dissolved and soluble in the oral cavity. Saliva, which is the liquid found in the oral cavity, is comprised mostly of water. Therefore, the film preparations of the present invention are "water" soluble films.

The Examiner also maintains that, in claims 1 and 2, the term "solid solution" is not clear since one is not able to ascertain whether the claim is referring to a solid or solution. This term renders claims 1 and 2 indefinite, as well as claims 3-11, since they are dependent from claims 1 and 2.

Applicants respectfully disagree with the Examiner's interpretation of the definition of the term "solid solution" as indefinite. The term "solid solution" is a term of art used within the scientific community to refer to "a homogenous solid that can exist over a range of component chemicals" (Reference: WordNet[®] 1.7, © 2001; Princeton University). Furthermore, in the context of pharmaceutical preparations, the term, "solid solution" can be found in U.S. Patent No. 6,264,981.

Lastly, the Examiner maintains that, in claim 7, the term "saccharide" lacks clear antecedent basis by depending from claims 1 or 2, which renders the claim indefinite.

Claim 7 has been canceled, thereby obviating this basis for rejection.

The claims, as amended, are fully compliant with all the requirements of §112 including the requirements of §112, second paragraph.

Claims 1-11 were rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Fuchs et al (U.S. Patent No. 4,136,145), in view of Tapolsky et al. (U.S. Patent No. 5,800,832) or Burns et al. (U.S. Patent No. 6,294,202).

The instant claims are directed to a soluble film preparation comprising a drug, edible polymer, and either a monosaccharide or an oligosaccharide, wherein the film is formed by spreading and drying and has an elution rate of more than about 50% per 10 minutes and wherein the drug is a compound that forms a solid solution with the edible polymer to enhance internal absorption. As shown in the Examples, the resulting thin film is obtained by spreading and drying which is a simple and economic production method that does not require a machine such as an extruder.

Fuchs may disclose a soluble film preparation for drug delivery but nowhere does the reference teach or suggest a soluble film preparation formed by spreading and drying and has an elution rate of more than about 50% per 10 minutes that contains both a drug and an edible polymer that forms a solid solution to enhance internal absorption of the drug.

The Tapolsky patent, which discloses bioerodable films for delivery of pharmaceutical compounds to mucosal surfaces, teaches that the incorporation of pharmaceutical components in films is well known in the art. However, as with the Fuchs reference, the Tapolsky patent does not disclose a film with an elution rate of more than about 50% per 10 minutes.

The Examiner further maintains that the Burns patent discloses compositions that comprise bioabsorbable polymers and drugs that can be prepared in the form of films that lose their structural integrity as a film after 3 minutes, and become totally dispersed within 20 minutes.

Applicants respectfully disagree with the Examiner's understanding of the Burns patent disclosure. Burns does describe a water soluble film that loses its structural integrity as a film in 3 minutes and becomes totally dispersed within 20 minutes. However, the "water soluble" test is conducted on film that is formed by drying an aqueous solution of 1% weight/weight (w/w) unmodified polyanionic polysaccharide in water. The Burns' film, in addition, does not have a drug, and of course, is completely different from the present film preparation comprising a specific drug, an edible polymer and a mono or oligosaccharide.

Furthermore, all compositions of a water soluble film and a drug do not have the same elution rate, but in fact, have different elution rates depending upon the composition of the constituents. Should the Examiner's position be correct, all compositions of a water soluble film and a drug will have the same elution rate. However, the data of the present application demonstrates otherwise. As shown in Examples 18 and 19, film preparations comprising a drug, HPC and reducing maltose starch syrup have superior elution rates than film preparations in Example 2 which consist of drug and HPC.

Consequently, one of ordinary skill in the art would not have been motivated to combine the teachings of Fuchs et al, Tapolsky et al, and Burns et al to achieve film preparations with the elution rates of the present invention.

Awamura, et al.
09/529,234

In summary, reconsideration of this application and the allowance of Claims 1-11 of this application as hereinabove amended in response to this communication are respectfully requested for the reasons stated above.

Finally, Applicants believe that additional fees are not required in connection with the consideration of this response to the currently outstanding Official Action. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge and/or credit Deposit Account No. **04-1105**, as necessary, for the correct payment of all fees which may be due in connection with the filing and consideration of this communication.

Respectfully submitted,

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